

Food and Drug Administration 2715 5 JUL 25 P2:16
Office of Nutritional Products, Labeling & Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740

June 09, 2005

JUN 6 2005

RE: Dietary Supplement Claims Notification

Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that the following product is manufactured, packed and/or distributed by Hillestad Pharmaceuticals at 178 US Highway 51N, Woodruff, WI 54568.

This notification is being provided pursuant to 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a).

Product Names: Summit B
B-Complex 50
Summit Stress
Stress Formula
Vitamin B12
B12 – 250
Vitamin B6
Vitamin B6 – 100
Niacin-50
PABA
Pantothenic Acid
All B-Complex
Folic 500 Formula

975 0162

LET 16400

The following statement(s) are or may be used on the labels and in the labeling of the products:

- *"The B vitamins are an important family of vitamins, which must be replenished regularly."*
- *"They are involved in a wide range of body functions including carbohydrate, fat and protein metabolism, production of red blood cells, and protein synthesis."*

HOME OFFICE:

Hillestad Pharmaceuticals U.S.A.
178 U.S. Highway 51 North
Woodruff, Wisconsin 54568-1700

MAILING ADDRESS:

Hillestad Pharmaceuticals U.S.A.
P.O. Box 1700 1
Woodruff, Wisconsin 54568-1700

(715) 358-2113 • 1-800-535-7742

(715) 358-7812 (FAX)

hill@newnorth.net (E-mail)

www.hillestadlabs.com

- *"They are also critical nutrients for the nervous system."*

I certify that the information in this notice is complete and accurate and that Hillestad Pharmaceuticals has substantiation that the statements are truthful and not misleading.

Sincerely,



Dan Hillestad
President

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